

PATENT
Docket No. 1758-4050

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Linda
5/20/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Francis MICHON et al.

Serial No. : 09/853,367

Group Art Unit: 1645

Filed : May 11, 2001

Examiner: DEVI, S.

For : IMMUNOGENIC COMPOSITIONS OF LOW MOLECULAR WEIGHT
HYALURONIC ACID AND METHODS TO PREVENT, TREAT AND
DIAGNOSE INFECTIONS AND DISEASES CAUSED BY GROUP A
AND GROUP C STREPTOCOCCI

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. §121

COMMISSIONER OF PATENTS
Washington, D.C. 20231

Sir:

In response to the restriction requirement mailed April 16, 2002, applicants provide the following comments and election. Claims 1-33 are pending and are subject to restriction, according to the Examiner, to one of the following inventions:

- I. Claim 1-18 and 29, drawn to an immunogenic conjugate molecule comprising hyaluronic acid covalently bound to a polypeptide carrier and a vaccine comprising the same, classified in class 424, subclass 197.11.
- II. Claims 19 and 20, drawn to a method of preparing a hyaluronic acid-polypeptide conjugate by reductive amination, classified in class 536, subclass 123.1.
- III. Claims 21-24 and 33, drawn to purified antibody to the conjugate molecule comprising hyaluronic acid covalently bound to a polypeptide carrier and an immunoassay kit comprising the same, classified in class 530, subclass 387.5.

Serial No.: 09/853,367

Socket No.: 1758-4050

- IV. Claims 25-28, drawn to a method of producing an antibody response by administering to a mammal a low molecular weight hyaluronic acid covalently bound to a polypeptide carrier, classified in class 436, subclass 547.
- V. Claims 30-33, drawn to a method of inhibiting streptococcal infection and progression of infection caused by HA-containing bacteria in a mammal, classified in class 424, subclass 244.1.

Applicants respectfully disagree that the Examiner's requirement is proper. However, in order to facilitate prosecution and to avoid a holding of non-responsiveness, applicants elect the claims of Group I with traverse.

The Examiner contends that Groups I and II are distinct because the product as claimed in Group I can be made by a materially different process as described in Group II. The Examiner contends that products of Group I may be produced by processes that do not involve reductive amination, for example, carbodiimide coupling. However, the method of Group II does not state that the conjugates of Group I can only be produced by processes that involve reductive amination. The instant specification states: "The LMW-HA may be coupled to a carrier by methods known in the art." (page 10, line 14). The process of reductive amination is simply a preferred method of coupling for the claimed conjugates, and thus the process of reductive amination is recited in a dependent claim (i.e., claim 20) to the general method (i.e., claim 19). Therefore, the restriction of Groups I and II is improper. Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

The Examiner contends that Groups I and III are drawn to two distinct products, a hyaluronic acid-polypeptide conjugate and an antibody. However, Group I and III are related because the antibodies of Group III are produced using the conjugates of group I and, accordingly, are specific to the conjugates of Group I. Thus, a search of these Groups does not seem to be overly burdensome.

The Examiner contends that the processes of Groups IV and V can be practiced with product materially different than the conjugates of Group I. The Examiner argues that a hyaluronic acid-containing microorganism admixed in a strong adjuvant may elicit an antibody response as claimed in Group IV. Groups IV and V should not be restricted because the method of group IV relates to a specific conjugate comprising isolated HA, capable of eliciting specific antibodies which confer protection against HA containing bacteria, i.e. Group V. The

Serial No.: 09/853,367

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Examiner's suggestion that group V relates to methods of protecting against infection using bacteria themselves is improper, as such a method is not based on applicants' claims which relate to the use of HA-protein conjugates, not bacteria.

In the event that the Examiner does not withdraw the requirement, applicants expressly reserve the right to file a divisional application to the presently non-elected subject matter or take appropriate action under 37 C.F.R. §§1.143-1.145.

Further, if the instant application's composition claims are determined to be new and nonobvious, then process of use claims which utilize the new and nonobvious compositions are therefore themselves new and nonobvious processes. (*In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995)). Further, as stated in *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973):

We would add, moreover, that in our view it is in the public interest to permit appellant to claim the process [of use] as well as the product. The result is to encourage a more detailed disclosure of the specific methods of using the novel composition he had invented in order to have support for the process claims.

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. 112, *all aspects of what they regard as their inventions, regardless of the number of statutory classes involved*. [Emphasis in original]

Applicants respectfully request reconsideration and withdrawal, or at a minimum, modification of the restriction requirement (37 C.F.R. §1.143).

Early and favorable action by the Examiner is earnestly solicited.

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Locket No.: 1758-4050

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 3842-4050. A DUPLICATE OF THIS SHEET IS ATTACHED.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Date: May 15, 2002

By:



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FROM/ATTORNEY: Kenneth H. Sonnenfeld

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Commissioner for Patents
Washington, DC 20231

CERTIFICATE OF FACSIMILE TRANSMISSION

Sir:

I hereby certify that the attached Response to Restriction Requirement Under 35 U.S.C.
§121 (4 pages plus 1 duplicate page) is being transmitted on the date shown below to Examiner
S. DEVI, Ph.D., at the following facsimile number: 703-308-4315.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: May 15, 2002

By:


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